DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-378/S-015

Serono, Inc.
Attention: Pamela Williamson Joyce
Vice President, Regulatory Affairs
One Technology Place
Rockland, MA 02370

Dear Ms. Williamson Joyce:

Please refer to your new drug application (NDA) dated August 3, 2001, received August 6, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gonal-f ® (follitropin alfa for injection).

We acknowledge receipt of your submissions dated July 8, August 30, 2002, January 30, 2003, and March 11 (2), and 18, 2004.

Your submission dated August 30, 2002, constituted a complete response to our February 28, 2002 approvable letter.

This supplemental new drug application provides for the following changes:

1) Change in manufacture of drug product from(b)(4)----------
2) Changes in the approved formulation for mon----------50 IU).
3) Change in container/closure system for mono-doses from ampules to vials.
4) New diluent for use with the single doses: pre-filled syringes with Sterile Water for Injection.
5) Change in storage condition for multi-dose (1,050 IU) after reconstitution.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and immediate container and carton labels).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-378/S-015." Approval of this submission by the FDA is not required before the labeling is used.

Please submit one marketing package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Archana Reddy, M.P.H., Regulatory Project Manager, at (301) 827 - 4260.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader for the
Division of Reproductive and Urologic Drug Products
Division of New Drug Chemistry II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Moo-Jhong Rhee

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